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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,093	12/17/2003	Richard E. Stein	279.B31US2	3171

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EXAMINER	
EVANISKO, GEORGE ROBERT	

ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,093	STEIN ET AL.	
	Examiner	Art Unit	
	George R. Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/30/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter which was not described in the original specification is the method or system having icons/lamps using "non-textual" pictorial graphic shapes, in combination with the other elements/steps set forth in the claims. Any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This rejection is related to new-matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 7-15, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeGroot (5987356). DeGroot shows a patient activator in figure 3, with patient query and delivery button, 102, audible generator, 112, and front indicator LEDs, 116. When the patient depresses button 102, the IMD is queried, and returns an indicator/status of the heart rhythm, such as therapy is warranted (AF, AT) or no therapy is warranted, using LEDs and/or audible generator (e.g. as discussed in columns 35-37). It is noted that the patient activator is meant to be carried by the patient and therefore meets the functional use of handheld and that an indication that therapy is warranted is an indication to contact a physician and also indicates information related to a condition of the implanted device in that it has or has not detected arrhythmia and is ready to deliver therapy (in the alternative, see below). In addition, DeGroot specifically states that the LEDs and/or audible indications presented on the activator can be changed using similar signals that allow a patient to distinguish between conditions (column 36, lines 63-67) providing a clear indication and motivation that the indicators can be modified. But DeGroot does not teach the use of deadfront status indicator lamps/icons being illuminated by LEDs or different colored LEDS, having the icons/lamps differentiated from each other by different non-textual pictorial graphic shapes, and using natural language messages to communicate the status information. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the status indication system and method as taught by DeGroot, with the use of deadfront status indicator lamps/icons being illuminated by LEDs or different colored LEDS, having the icons/lamps differentiated from each other by different non-textual pictorial graphic shapes, and using natural language messages to communicate the status information since it was known in the art that status indication systems

and methods use deadfront status indicator lamps/icons being illuminate by LEDs or different colored LEDS, having the icons/lamps differentiated from each other by different non-textual pictorial graphic shapes, and using natural language messages to communicate the status information to provide the predictable results of: allowing the operator to use their visual sense to determine the status of the device which can aid in noisy environments; allowing the device to clearly indicate the status to allow the operator to easily distinguish between different conditions; allowing caregivers to more quickly and efficiently perform the required steps or to allow caregivers not familiar with that country's language/text to still operate the device and perform the correct steps; and allowing natural voice/language messages so the operator does not get confused between different tones and does not have to remember what different tones mean.

In the alternative, for the handheld device, the indication for contacting a physician, and receiving information about the condition of the IMD, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the patient query and status indication system and method as taught by DeGroot, with the system being handheld, having an indicator for contacting a physician, and to receive information related to a condition of the IMD since it was known in the art that patient query and status indication systems and methods use devices that are handheld so the device can be easily carried and used by the patient, to use an indicator for contacting a physician to allow the patient to know when to seek help, and to receive information related to a condition of the IMD to allow the physician to determine whether the IMD needs to be replaced or reprogrammed.

Claims 1-4, 7-16, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Musley et al (2004/0210256). Musley shows a patient activator in figure 1, with patient query button, "?", and a delivery button, "Z", and front indicator LEDs, 62-68. When the patient depresses button "?", the IMD is queried, and returns an indicator/status of the heart rhythm, such as AF present, call physician, or no AF present, using LEDs (e.g. as discussed in paragraph 40). It is noted that the patient activator is meant to be carried by the patient and therefore meets the functional use of handheld and would also contain a self contained power supply to activate the LEDs, and the LEDs also indicate information related to a condition of the implanted device in that it has or has not detected arrhythmia and is ready to deliver therapy (in the alternative, see below). But Musley does not teach the use of deadfront status indicator lamps/icons being illuminated by LEDs or different colored LEDS, having the icons/lamps differentiated from each other by different non-textual pictorial graphic shapes, and using natural language messages to communicate the status information. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the status indication system and method as taught by Musley, with the use of deadfront status indicator lamps/icons being illuminated by LEDs or different colored LEDS, having the icons/lamps differentiated from each other by different non-textual pictorial graphic shapes, and using natural language messages to communicate the status information since it was known in the art that status indication systems and methods use deadfront status indicator lamps/icons being illuminate by LEDs or different colored LEDS, having the icons/lamps differentiated from each other by different non-textual pictorial graphic shapes, and using natural language messages to communicate the status information to provide the predictable results of: allowing the operator to use their visual sense

to determine the status of the device which can aid in noisy environments; allowing the device to clearly indicate the status to allow the operator to easily distinguish between different conditions; allowing caregivers to more quickly and efficiently perform the required steps or to allow caregivers not familiar with that country's language/text to still operate the device and perform the correct steps; and allowing natural voice/language messages so the operator does not get confused between different tones and does not have to remember what different tones mean.

In the alternative, for the handheld device, the self contained power supply, and the information related to a condition of the IMD, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the patient query and status indication system and method as taught by Musley, with the system being handheld, having a self contained power supply, and receiving information related to a condition of the IMD since it was known in the art that patient query and status indication systems and methods use devices that are handheld so the device can be easily carried and used by the patient, to use a self contained power supply to allow the patient to travel freely and untethered to an electrical socket, and to receive information related to a condition of the IMD to allow the physician to determine whether the IMD needs to be replaced or reprogrammed.

Claims 5, 6, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeGroot or Musley (for claims 5, 6, and 17) as applied to the claims above.

DeGroot or Musley disclose the claimed invention except for the different patient rhythms and indications, such as a fast rhythm for 48 hours and the simultaneous use of two indicators of four and no other visual or audible indicators (claims 5, 6, 17), and the use of two

separate buttons to query the device and to apply the shock (claim 16). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the patient query and status indication system and method as taught by DeGroot or Musley, the different patient rhythms and indications, such as a fast rhythm for 48 hours and the simultaneous use of two indicators of four and no other visual or audible indicators and the use of two separate buttons to query the device and to apply the shock since it was known in the art that patient query and status indications systems and methods use different patient rhythms and indications, such as a fast rhythm for 48 hours and the simultaneous use of two indicators of four and no other visual or audible indicators to allow the physician to dictate what information should be displayed to the patient based on the patients particular condition and the use of two separate buttons to query the device and to apply the shock to prevent the operator from getting confused on what button or button sequence is necessary to query and/or deliver the shock.

Response to Arguments

Applicant's arguments filed 7/30/07 have been fully considered but they are not persuasive.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

The statement that the Examiner is taking official notice in the single-reference obviousness rejections under 103 and Applicant requests references to support the assertions is acknowledged. Although, the Examiner previous provided the evidence/references in the last office action and the evidence is repeated below in the conclusion. Note that Hamilton shows the use of different non-textual pictorial graphic shapes for the lamps/icons.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hamilton et al and Nelms et al are two examples of many showing medical status devices that use backlit icons, i.e. using LEDs to light the icons, and provides natural language voice messages to convey information. Adams and Adams et al are two examples of many showing the use of handheld interrogators and providing indications of when to contact a physician. Tacker et al and Stanton et al are two examples of many showing the indication of information related to the condition of an IMD. Nappholz et al is one example of many showing the use of different rhythms and indications that can be provided to the patient.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

George R Evanisko
Primary Examiner
Art Unit 3762
10/13/7

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10/13/07